

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	EPIVIR ORAL SOLUTION
Synonym(s)	EPIVIR ORAL SOLUTION 10 MG/ML * EPIVIR/3TC ORAL SOLUTION 10 MG/ML * 3TC ORAL SOLUTION 10 MG/ML * EPIVIR JARABE * EPIVIR SIROP * EPIVIR SOLUCION ORAL * EPIVIR SOLUTION BUVABLE * NDC NO. 0173-0471-00 * LAMIVUDINE, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
LAMIVUDINE	134678-17-4	1	
NON-HAZARDOUS INGREDIENTS	Unassigned	99	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: abdominal pain; headache; nausea; vomiting; fatigue; rash. Exposure might occur via ingestion; skin; eyes. Health effects information is based on hazards of components.</p>
Environment	No environmental hazards have been identified for this material.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
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Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	No special requirements needed.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	LAMIVUDINE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	600 mcg/m ³ (8 HR TWA)	REPRODUCTIVE HAZARD

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Other Equipment or Procedures None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Solution.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This preparation contains ingredient(s) with the following activity: an anti-viral agent.

Target Organ Effects No specific target organ effects have been identified.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity Not expected to be genotoxic, based on effects of individual components.

Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Contains components which have been classified as: Possible risk of toxicity in developing human offspring.

Other Adverse Effects The following adverse effects have been noted with therapeutic use of this material: abdominal pain; headache; nausea; vomiting; fatigue; rash.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Microbial Growth Inhibition This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

Minimum Inhibition Concentration:

- > 1000 mg/l, , Azotobacter beijerinckii
- > 1000 mg/l, , Pseudomonas aeruginosa
- > 1000 mg/l, , Trichoderma harzianum
- > 1000 mg/l, , Aspergillus niger
- > 1000 mg/l, , Nostoc commune

Algal This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 96.9 mg/l, 72 Hours, Selenastrum capricornutum, green algae

NOEC: > 96.9 mg/l, 72 Hours, Selenastrum capricornutum, green algae

Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

NOEC: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

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	Chronic EC50:	> 100 mg/l, 7 Days, Ceriodaphnia dubia, 7 day static renewal
	Chronic LOEC:	> 100 mg/l, 7 Days, Ceriodaphnia dubia
	Chronic NOEC:	100 mg/l, 7 Days, Ceriodaphnia dubia
Fish	This material contains an active pharmaceutical ingredient that is not toxic to fish.	
	Juvenile Oncorhynchus mykiss, rainbow trout	
	EC50:	> 97.7 mg/l, 96 Hours, Static test
MOBILITY		
Solubility	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.	
Volatility	This material contains an active pharmaceutical ingredient that will not readily enter into air from water.	
	Henry's Law Constant	1.00E-13 atm m ³ /mol, Estimated
Adsorption	This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment.	
	Soil Sediment Sorption (log K _{oc}):	1.5 to 2.03, Measured
Partitioning	This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.	
PERSISTENCE/DEGRADATION		
Hydrolysis	This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.	
	Half-Life, Neutral:	> 1 Years, Measured
Photolysis	This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.	
	UV/Visible Spectrum:	271 nm at pH 7
Biodegradation	This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).	
	Aerobic - Ready	
	Percent Degradation:	< 1 %, 28 days, Modified Sturm test.
	Aerobic - Inherent	
	Percent Degradation:	4 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
	Aerobic - Inherent	
	Percent Degradation:	0 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge
	Aerobic - Soil	
	Percent Degradation:	15 to 24 %, 64 days
Bioaccumulation	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.	

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

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UN Classification and Labelling**Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)**Classification**

This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations**TSCA Status**

Exempt

16. OTHER INFORMATION

References

GSK Hazard Determination

SDS Version Number

12

SDS Sections Updated**Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

Subsections

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.